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No. 95-116

In The

Supreme Court of the United States

October Term, 1995

DONNA WINTERS, an individual person,

Petitioner,

vs.

COSTCO WHOLESALE GROUP BENEFITS PROGRAM and CONCEPT ADMINISTRATORS, INC.,

Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BEST AVAILABLE COPY

MOTION OF NORTHWEST WOMEN'S LAW CENTER, CALIFORNIA WOMEN'S LAW CENTER, CONNECTICUT WOMEN'S EDUCATION AND LEGAL FUND, EMPLOYMENT LAW CENTER A PROJECT OF THE LEGAL AID SOCIETY OF SAN FRANCISCO, EQUAL RIGHTS ADVOCATES INC., FEMINIST MAJORITY FOUNDATION, LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC., NATIONAL BLACK WOMEN'S HEALTH PROJECT, NATIONAL CENTER FOR LESBIAN RIGHTS, NATIONAL COALITION FOR CANCER SURVIVORSHIP, AND NATIONAL WOMEN'S LAW CENTER FOR LEAVE TO FILE BRIEF *AMICI CURIAE* IN SUPPORT OF PETITION AND BRIEF *AMICI CURIAE*

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Amici curiae, the Northwest Women's Law Center, the California Women's Law Center, *et al.*, hereby move, pursuant to Rule 37.2, for leave to file a brief of *amici curiae* in support of the writ of certiorari to the United States Court of Appeals for the Ninth Circuit in *Winters v. Costco Wholesale Group Benefits Program, et al.* Petitioner has consented to the filing of this brief, but respondents have declined to consent. A copy of the proposed *amici brief* is attached.

INTEREST OF THE *AMICI CURIAE*

Amici curiae are 11 women's rights, civil rights and health care advocacy groups sharing a strong commitment to the protection of the rights of women and the assurance that women have equal access to health care and health insurance coverage. *Amici curiae* engage in litigation, legislation and education to assure that women are not discriminated against in the delivery of health insurance. Individual statements of interest of *amici* are as follows:

Northwest Women's Law Center

The Northwest Women's Law Center (the "Law Center") is a non-profit legal organization dedicated to advancing and protecting the legal rights of women through litigation, education, legislation and a legal information and referral phone line. The Law Center provides these services to women in Washington, Alaska, Montana, Idaho and Oregon. Since its founding in 1978, the Law Center has worked to ensure that women have access to health care and the protection of health care insurance in a non-discriminatory and equitable manner. The Law Center has worked on legislative initiatives on health care and insurance reform both locally and nationally. The Law Center has also participated as *amicus curiae* in several insurance discrimination cases throughout the country.

California Women's Law Center

The California Women's Law Center ("CWLC") is a private, nonprofit public interest law center specializing in the civil rights of women and girls. CWLC was established in 1989 to address the comprehensive civil rights of women and girls in the following areas: Sex Discrimination, Reproductive Rights and Health Care, Family Law, Violence Against Women and Child Care. The CWLC has placed a strong emphasis on addressing gender bias in health care. In addition, the CWLC has initiated the Breast Cancer Legal Clinic to provide advocacy and legal advice to breast cancer survivors and to address the systemic barriers that prevent women from accessing the health care they need and to which they are entitled. This case raises questions within the expertise and concern of the California Women's Law Center.

Employment Law Center a Project of the Legal Aid Society of San Francisco

The Employment Law Center ("ELC"), a project of the Legal Aid Society of San Francisco, is a private non-profit, public interest law firm which represents indigent workers in cases involving employment discrimination and workplace rights. The ELC specializes in, among other areas of the law, sex discrimination and employee benefits. Health coverage is an important employment benefit and the ELC is committed to insuring that women employees have access to non-discriminatory health insurance coverage.

Equal Rights Advocates, Inc.

Now in its twenty first year, Equal Rights Advocates is one of the country's oldest women's law centers dedicated to the empowerment of women through the establishment of their

economic, social and political equality. The organization has a long history of interest, activism, and advocacy in all areas of law which affect equality between the sexes. ERA has represented women in cases challenging lack of access to insurance benefits and joined as *amicus* in Title VII cases brought to assure equal treatment of the sexes in annuity plans.

Connecticut Women's Education and Legal Fund, Inc. (CWEALF)

The Connecticut Women's Education and Legal Fund, Inc. ("CWEALF") is a non-profit women's rights organization incorporated in 1973. We have over 1,400 members. Our mission is to work through legal and public policy strategies and community education to end sex discrimination and to empower all women to be full and equal participants in society. We seek to join this brief as *amicus curiae* because we support the need for increased medical research on women's health issues and understand that many women are excluded from lifesaving treatments because those treatments are deemed "experimental".

The Feminist Majority Foundation

Founded in 1987, the Feminist Majority Foundation is a 501(c)(3) non-profit organization with offices in Arlington, Virginia and Los Angeles, California. The Feminist Majority Foundation seeks to empower women through research, education, action and other strategies that bring about women's equality. The Feminist Majority Foundation believes that the precedent set in *Winters v. Costco* will have a significant negative impact on women's health care and that the ruling, as it presently stands, will have a disproportionately negative impact on women.

Lambda Legal Defense

Lambda is the nation's oldest and largest non-profit organization dedicated to the civil rights of lesbians, gay men and all people with HIV/AIDS. Since 1983 and its initiation of the first AIDS discrimination case, Lambda has had a strong, continuing interest and involvement in the development of fair and rational policies relating to HIV/AIDS, particularly in the area of insurance and access to health care. Because of the relatively short time during which HIV/AIDS has been recognized, and the limitations of HIV-related therapies currently approved by the Food and Drug Administration, the standard of care for HIV disease can include life-saving treatments for which studies documenting their efficacy are still in progress. Lambda believes that the failure to apply the long-established doctrine of *contra proferentem* to self-insured plans is inherently discriminatory and seriously detrimental to the lives and health of people with HIV disease who rely on these plans for their healthcare.

National Center for Lesbian Rights (NCLR)

The National Center for Lesbian Rights ("NCLR"), formerly the Lesbian Rights Project, is a non-profit public interest law firm founded in 1977 and devoted to the legal concerns of women who encounter discrimination on the basis of their sexual orientation. As a nationally recognized source of technical support and information on issues of lesbian health, NCLR is particularly well-suited to offer *amicus* assistance to this court in this matter. NCLR has published an extensive bibliography of research on lesbian health matters, which includes over eight hundred citations. NCLR is among the founders of the Washington, D.C. based Lesbian Health Advocacy Network, which provides information on women's access to health care, including its regulation by the insurance industry. We are regularly called upon

to provide information for federal health programs and for national conferences addressing women's health concerns.

National Black Women's Health Project (NBWHP)

The National Black Womens' Health Project ("NBWHP") is a self-help and health advocacy organization committed to improving the health of Black Women. The organization has 16 chapters and has members in 42 states. Studies have shown that women, especially women of color, often are given inferior information and fewer treatment options than others. The impact of these inequities result in disparate health outcomes and mortality rates. Therefore, NBWHP believes that patients and physicians should be allowed the widest possible latitude and choice in determining the best course of treatment. Insurance plan administrators should not be allowed absolute discretion in determining whether a treatment or procedure is "medically appropriate or necessary."

National Coalition for Cancer Survivorship (NCCS)

NCCS, a coalition of 2,500 individuals and organizations, represents tens of thousands of members and constituents in the cancer survivorship movement in the United States. NCCS members include leaders of cancer survivor community organizations, regional and national cancer-related organizations, and many of the nation's most prestigious cancer treatment institutions. Through public education and advocacy, NCCS works to expand the right to adequate health insurance to the nearly 9,000,000 cancer survivors of the United States.

National Women's Law Center

The National Women's Law Center is a Washington-based legal organization which has been working since 1972 to advance

and protect women's legal rights. The Center's primary goal is to ensure that public and private sector practices and policies better reflect the needs and rights of women. Access to quality health care and adequate health insurance is of profound importance to the lives of women throughout the country, and the National Women's Law Center has a long history of working to achieve that goal.

REASONS FOR GRANTING THE MOTION

Amici curiae are in a unique position to address the questions presented by this case and to bring additional reasons to the Court's attention why the writ should be granted. This case presents important issues of law that deserve the fullest and most informed discussion possible. *Amici* offer a particular expertise concerning the importance of this case to women and why it is important for this Court to grant review of the Ninth Circuit's opinion. The proposed brief of *amici curiae* explains the implication of the *Winters v. Costco* decision for women, describing the disproportionate impact the decision will have on women who are beneficiaries of health insurance plans under the Employee Retirement Income Security Act (ERISA). One significant result of the *Winters* decision is to make it easier for ERISA plan administrators to deny insurance coverage for medical treatments unless the treatments are supported by an abundance of scientific data. Consequently, women beneficiaries of ERISA plans will disproportionately suffer because, historically, research into women's health care has been under-funded and under-researched, resulting in a paucity of scientific data needed to support insurance coverage.

The brief of *amici* demonstrates the way in which the lack of funding and research of women's diseases has led to a lack of data and information about women's health care. It further demonstrates that if the Ninth Circuit decision in *Winters* is

upheld, this lack of data will lead to an increase in insurance coverage denials for women, particularly women in need of life-saving medical treatments. The brief of *amici* further explains how the *Winters* decision creates an unfair and unjust imbalance of power between insurance companies and insurance consumers and how the *Winters* decision makes an unprincipled distinction between beneficiaries of ERISA health plans and beneficiaries of private health care plans.

Amici contend that this brief includes information and arguments that are presented in neither the brief of petitioner nor the brief of respondent. *Amici* believe that the information and arguments will be meaningful and useful to this Court in weighing the implications of the *Winters* decision and in making the decision whether to grant the writ.

It is respectfully requested that the Court grant leave to file the attached brief of *amici curiae*.

Respectfully submitted,

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INTEREST OF THE *AMICI CURIAE*

Amici curiae are 11 women's rights, civil rights and health care advocacy groups sharing a strong commitment to the protection of the rights of women and women's access to health care and health insurance coverage. *Amici curiae* engage in litigation, legislation and education to assure that women are not discriminated against in the provision of health insurance. Individual statements of interest of amici are set forth in the motion for leave to file a brief of *amicus curiae* in support of petition for writ of certiorari, submitted with this brief.

The case before the Court is of great importance to *amici* because of the disproportionate effect the Ninth Circuit ruling will have on women attempting to obtain health insurance coverage for important medical treatments and procedures.

STATEMENT OF THE CASE

This *amicus* brief supports Petitioner Donna Winters' brief in *Winters v. Costco Wholesale Benefits Program and Concept Administrators, Inc.*, 49 F.3d 550 (9th Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 3068 (U.S. July 18, 1995) (No. 95-116). For a review of the facts of the case and proceedings, the *amici curiae* respectfully refer the Court to the brief of the Petitioner. The *amici curiae* join Donna Winters in requesting that this Court grant the petition for review to resolve the current Circuit court split and determine whether and to what extent the doctrine of *contra proferentem* applies to insurance plans under the Employee Retirement Income Security Act (hereinafter "ERISA").

SUMMARY OF THE ARGUMENT

This case involves the standard of review that courts should

use when reviewing insurance coverage decisions made by ERISA insurance plan administrators. In *Winters v. Costco*, the Ninth Circuit rejected the long held doctrine of *contra proferentem* — the doctrine which requires courts to construe ambiguities in insurance contracts in favor of coverage for the beneficiaries — as it applies to ERISA health insurance plans. Consequently, the decisions made by plan administrators under ambiguous contract terms will be reviewed for an abuse of discretion only.

One result of this decision is that ERISA plan administrators will have broader discretion to deny insurance coverage for medical treatments unless the treatments are supported by an over-abundance of scientific data. *Amici* argue that women beneficiaries of ERISA plans will disproportionately suffer as a consequence of the *Winters* decision because, historically, research into women's health care has been under-funded and under-researched resulting in a paucity of the type of scientific data needed to support insurance coverage claims.

The brief of *amici* further argues that the *Winters* decision creates an unfair and unjust imbalance of power between insurance companies and insurance consumers and that the *Winters* decision makes an unprincipled distinction between beneficiaries of ERISA health plans and beneficiaries of private health care plans. *Amici* believe that the failure to apply the long-established doctrine of *contra proferentem* to ERISA health insurance plans is inherently discriminatory and seriously detrimental to the lives and health of women who rely on these plans for their health care coverage.

REASONS FOR GRANTING THE WRIT

I.

REJECTION OF THE DOCTRINE OF *CONTRA PROFERENTEM* FOR ERISA HEALTH PLANS WILL RESULT IN DECREASED COVERAGE FOR INSURANCE CONSUMERS AND WILL DISPROPORTIONATELY AFFECT WOMEN CONSUMERS DUE TO THE LACK OF DATA ON WOMEN'S HEALTH ISSUES.

A. The Rejection of the Doctrine of *Contra Proferentem* has a Disproportionate Effect on Female Beneficiaries of ERISA Health Plans.

The rule of *contra proferentem* states that courts are to construe ambiguities in insurance contracts in favor of coverage for the insured. *Kunin v. Benefit Trust Life Ins.*, 910 F.2d 534 (9th Cir. 1990). The doctrine was developed by courts to protect consumers of health insurance from ambiguous or unclear insurance contracts and to insure that the drafters of such contracts not be allowed to benefit from their own poorly drafted or deliberately vague contracts. The doctrine is important because it provides an incentive for insurance companies to describe with specificity what is covered or excluded in a contract and provides a disincentive to companies who might otherwise seek to disguise or make ambiguous those provisions that exclude coverage. The doctrine of *contra proferentem* allows insurance companies to draft their own contracts, but protects insurance consumers in the event coverage decisions are made pursuant to ambiguous exclusionary provisions. Consequently, the doctrine has been very important to consumers because it has helped put them on more equal footing with their insurance companies.

In *Winters*, the Ninth Circuit held that the rule of *contra*

proferentem does not apply to self-funded health plans under ERISA where the plan administrator has expressly reserved authority to determine benefit eligibility. Under *Winters*, beneficiaries of ERISA plans who are denied coverage under vague or ambiguous exclusionary provisions may successfully challenge the denial only if the insurance plan administrators are shown to have abused their discretion. If upheld, this ruling will result in consumers of self-funded ERISA plans having less access to coverage than many other health insurance consumers, who may retain the ability to challenge ambiguous exclusionary provisions under *contra proferentem*. There is no principled basis for this distinction between consumers whose health insurance is under an ERISA plan, and those whose health insurance is private.

In particular, this decision will have a disproportionate impact on women because treatments for women's health issues[1] are more likely to fall into the contested area of ambiguous exclusionary provisions. Typically, insurance companies exclude from coverage treatments defined as "experimental and/or investigational," or "not medically necessary." Whether a particular treatment or procedure will be included under one of these exclusionary provisions is generally determined by the availability of medical data to support the efficacy of a particular treatment. Michael R. Testerman, Legal Challenges to Denials of Insurance Coverage for "Experimental Medical Treatments", 89 Mo. Med. 4 (1992). Because women's health issues have been historically under-researched, resulting in a paucity of medical data, women seeking medical treatments are disproportionately the targets of insurance companies seeking to invoke ambiguous exclusionary provisions such as "experimental and/or

1. Women's health issues have been defined as "diseases or conditions that are unique to women, are more prevalent or more serious in women, or for which specific risk factors or interventions differ for Women." H.R. 5393, 101st Cong. 2d. Sess. (Women's Health Equity Act of 1990).

investigational," or "not medically necessary."[2] The lack of research and data on women's health issues also makes it more difficult for women to challenge denials under one of these exclusionary provisions. This is true because plan administrators need only show that the denial was not an abuse of discretion and do not need to show that it was reasonable. The discretion given to plan administrators under *Winters* will result in women having a higher susceptibility to coverage denials and a decreased ability to successfully challenge these denials.

Under *Winters*, women will disproportionately suffer from the loss of protection provided by the doctrine of *contra proferentem* because plan administrators, acting on behalf of insurance companies, will be virtually unchallenged when they assert that there is not enough medical data to establish that a particular treatment is appropriate. Prior to *Winters*, women beneficiaries were able to challenge a contract's ambiguous provisions to compel coverage for cancer treatments — primarily for breast and ovarian cancer — through the doctrine of *contra proferentem*. These women beneficiaries being denied coverage were given the opportunity to present medical evidence to demonstrate that the treatment they were seeking did not fall under a particular ambiguous exclusionary provision and that it had efficacy for the particular illness. The practical result of the *Winters* holding is that insurance plan administrators will now have virtually complete discretion to make determinations

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2. In making these decisions, the insurer essentially renders a determination that either the insured's proposed treatment is not an appropriate remedy for the condition or the condition does not require the medical attention requested by the insured. It should be noted that insurers often issue denials despite the recommendation for treatment by the treating physician and an insufficient claims review process. Thus, if a particular treatment is not known to produce a cure or satisfactory result for a particular condition, it may be deemed "experimental," "investigational," and/or "not medically necessary" and accordingly not covered. Testerman, 89 Mo. Med. 4.

regarding coverage issues, short of an abuse of discretion, and the lack of data regarding women's health issues will mean decreased coverage for women.

B. Women's Health Issues Have Been Historically Under-Funded and Under-Researched, Resulting in Relatively Limited Medical Data.

Until recently, women's health issues have received scant attention from the scientific, medical, and political communities. 100 U.S. Pub. Health Service 73 (Women's Health: Report of the Public Health Service Task Force on Women's Health Issues) (1985); Cynthia Costello and Anne J. Stone eds. (W.W. Norton 1994), The American Woman: Where We Stand; Judith H. LaRosa and Vivian W. Pinn, Gender Bias in Medical Research, 48 J. Am. Med. Women's Ass'n 5 (1993). Public health experts as well as the federal government have now acknowledged and criticized the under-funding and lack of attention paid to women's health issues and the widespread exclusion of women from important medical study groups. *Id.* The impact of this neglect has resulted in an absence of research data available to support insurance coverage for the treatment of women's illnesses.

The first large scale documentation of the neglect of women's health research was a 1985 report by the Public Health Service Task Force on Women's Issues detailing the health status of American women. The Task Force was convened in response to a concern that women's health issues were being under-researched and that women were being excluded from clinical drug trials. *Id.* The Task Force Report concluded that lack of data on women resulted in a limited understanding of women's health care needs and the medical services women require. *Id.* The Report recommended that "... a systemic effort be made to address issues relating to gender bias in research and clinical

practice," and that, "biomedical and behavioral research be expanded to ensure emphasis on conditions and diseases unique to, or more prevalent in, women in all age groups." *Id.*

In response to the Task Force Report, the National Institutes of Health (NIH) "promulgated a policy to ensure that women were included in study populations." *Id.* at 5. Unfortunately, the NIH has made little progress towards this goal. A 1990 Government Accounting Office (GAO) report concluded that the NIH had done very little to implement its own policy and that women's health was still under-researched. National Institutes of Health: Problems for Implementing Policy on Women in Study Populations: Hearings Before the Subcomm. on Health and the Environment of the Comm. on Energy and Commerce, 101st Cong., 2d Sess. (1990) (statement of Mark V. Nadel, Assoc. Dir., National and Public Health Issues Human Resources Division), at 2. Under-funding has contributed to the inability to provide substantial amounts of data on the appropriate treatments for diseases primarily affecting women.

Following the 1985 Public Health Service Report, the Women's Health Advisory Committee issued a report in 1987 which detailed an institute by institute account of resources committed to women's health. Comprehensive Report of the Office of Research on Women's Health, U.S. Dept. Of Health and Human Services at 1. The Committee calculated that only 13.5% of the NIH overall budget in 1987 went to women's health research. *Id.* The NIH is the principal federal agency supporting biomedical research. National Institutes of Health: at 2.

> [N]ot only were women being left out of research on diseases that affect both sexes, but just 13.5% of the total NIH budget was being used to look at breast cancer, all gynecological cancer, infertility, pregnancy

> and contraception. Conditions such as fibroid tumors of the uterus, endometriosis, menstrual cramps, and premenstrual syndrome — all of which are quite common — were being virtually ignored. And diseases such as arthritis, Alzheimer's, and osteoporosis — which primarily affect women — were also being shortchanged.

Leslie Laurence and Beth Weinhouse, *Outrageous Practices: The Alarming Truth About How Medicine Mistreats Women* (1994).

Today breast cancer remains the most common form of cancer in women, and the second leading cause of cancer related deaths. H.R. 5393 (Women's Health Equity Act). One in eight women in the United States will be diagnosed with breast cancer during her lifetime. Jay R. Harris, *et al.*, Medical Progress: Breast Cancer, 327 New Eng. J. Med. 319 (1992). The risk of breast cancer has increased exponentially, more than doubling since 1960. African American women have experienced a steadily increasing mortality rate which has exceeded that of white women. *Id.* As recently as 1989, only $77 million was budgeted for all breast cancer research and of this amount, only $17 million was spent on basic research which focuses on the origins of the disease. H.R. 5393 (Women's Health Equity Act). While the total dollars dedicated to breast cancer research have increased significantly from 1991-1994, breast cancer research still consists of less than 9% of the National Cancer Institute's total cancer research budget. Cancer and AIDS Research Funding Trends, National Cancer Institute Financial Management Branch, 1994 Bypass Budget Request.

Such studies confirmed the general lack of funding and attention paid to women's health issues and specifically identified a critical area of discrimination — women have

systematically been excluded from clinical studies in nearly all areas of general medical research.[3] National Institutes of Health: at 2; Costello & Stone at 91-108. Even when efforts were made to include women in study groups, women were not included in relevant numbers and the data was not analyzed in a manner that would reveal the particular health effects on women. R.B. Merkatz, *et al.*, Women in Clinical Trials of New Drugs: A Change in Food and Drug Administration Policy, 329 New Eng. J. Med. 292, 293 (1993). In 1977, Food and Drug Administration (FDA) guidelines stated that "in general, both sexes [should have] substantial representation in clinical trials before FDA approval of drugs". *Id.* Despite adequate participation by both men and women, however, the data from the female participants was never isolated and analyzed to determine whether there were gender differences in the data. *Id.* The absence of such analysis undercuts any of the potential benefits of female participation in these clinical trials.

Further, the 1977 FDA guidelines on the participation of women in drug evaluations excluded a majority of the female population because it specifically excluded virtually all women with "child-bearing potential" from everything but the final phases of drug studies.[4] *Id.* Only after the FDA had sufficient

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3. Various justifications have been cited for this wholesale exclusion of women, including the complexity and cost of accounting for women's hormonal cycles, the availability of identifiable, convenient cohorts such as veterans or army recruits who are primarily male, and the concern that women in their childbearing years may become pregnant and expose the fetus to potential risks. Judith H. LaRosa and Vivian W. Pinn, *Gender Bias in Medical Research*, 48 J. Am. Med. Women's Ass'n 5 (1993).

4. Women fitting this definition included (1) pre-menopausal women who were sexually active and using no contraception; (2) women who were using oral, injectable or mechanical contraception; (3) women whose partners had vasectomies; (4) women who were sexually inactive; and (5) lesbians. R.B. Merkatz, 329 New Eng. J. Med. 292.

analysis as to the safety of a new drug could women with the capacity to become pregnant participate in later phases of studies. Only women with life-threatening diseases were allowed to participate in the early phases of drug trials. Most often, the justifications behind the exclusion were the legal and ethical issues surrounding the potential exposure to the fetus. Anna C. Mastroianni, *et al.* Eds., Women & Health Research, Ethical & Legal Issues of Including Women (National Academy Press 1994). Notwithstanding recent FDA changes in these practices, women's research remains underdeveloped. As a result, treatment for certain diseases is susceptible to being challenged as "experimental and/or investigational" by plan administrators, on behalf of insurance companies, seeking to limit the cost of providing health care benefits to their insureds.

As a result of the traditional rationales for excluding women from drug testing, researchers have excluded women from many clinical trials in which the need for their inclusion would seem self-evident. For example, cardiovascular disease is the number one cause of death and disability in American women, and yet women have been excluded from almost all major clinical trials on heart disease. R.B. Merkatz, at 64. In a leading study of coronary heart disease, known as the Lipid Research Clinic-Coronary Primary Prevention Trial, that ran from 1967 to 1983, women were excluded entirely, in part because it would have increased the cost of the study. LaRosa and Pinn at 147. The seminal study of the use of aspirin as a preventative therapy for coronary disease, The Physicians Health Study, included 22,701 men and no women. Laurence and Weinhouse at 61. The Multiple Risk Factor Intervention Trials, known as the Mr. Fit study, used a population of 13,000 men and no women to do a long term study of lifestyle factors related to cholesterol and heart disease. Laurence and Weinhouse at 61. As a result, doctors and scientists still do not know whether dietary change and exercise can benefit women in preventing heart disease. *Id.*

Women were even excluded for the first 20 years of the country's most significant study to date regarding aging, despite the well-established fact that women on average live longer than men.[5] *See* Normal Human Aging, the Baltimore Longitudinal Study (Bethesda, MD: US Dept. Of Public Health, 1994) NIH Publication #84-2450.

The nature of AIDS and the status of AIDS research, particularly in the treatment of women, underscores the dangers of endorsing a standard of review that effectively precludes the insured's ability to challenge the denial of coverage under "experimental and/or investigational" exclusions. Many treatments for AIDS are still the focus of continuing investigation, while others are rapidly developing. Mark Scherzer, Insurance and AIDS (16.05[2], 16-25, in Sexual Orientation and the Law, Release #7 (Nov. 1994). As a result, treatment of those with HIV disease often requires the use of therapies known to be effective long before there is an abundance of formal data to support the efficacy. National Commission on Acquired Immune Deficiency Syndrome, HIV Disease in Correctional Facilities (March 1991) at 14.

The lack of formal data supporting the use of effective AIDS treatments is of particular concern to women because the participation of women in AIDS clinical research is disproportionately low. Since funding of AIDS research began around 1982,[6] almost all funding and research on AIDS has been directed towards men.[7] As of early 1993, 21,598 people were

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5. A 1992 study by the National Center for Health Statistics indicates that a female's life expectancy at birth is almost seven (7) years longer than a male's life expectancy. Costello and Stone at 111-15.

6. National Cancer Institute Research Dollars by Variuos Cancer, Updated March 1995.

7. While some clinical research has focused on women as subjects, the (Cont'd)

enrolled in U.S. AIDS Clinical Trial Group studies, but only 1,952 were adult women. J. A. Koruck, Trends in Federally Sponsored Clinical Trials, Until the Cure: Caring for Women with HIV (Yale University Press 1993). When the Food and Drug Administration approved the AIDS drug AZT in 1987, not one of the sixty-three federally funded studies had evaluated the drugs toxicity or efficacy in women. Laurence and Weinhouse at 5. This exclusion is particularly alarming in view of the fact that women are the fastest growing population group afflicted with AIDS and AIDS related illnesses have been the fourth leading cause of death among U.S. women ages 25-44 since 1992.[8]

The chronicle of the exclusion of women from medical studies underscores the disadvantages facing women who seek to present medical data to challenge a denial of coverage. Due to the exclusion of women from clinical trials, women are more likely to need treatments that are subject to ambiguous exclusionary labels such as "experimental and/or investigational," than are men for whom substantial medical data exists. 100 U.S. Pub.

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primary research inquiry has been how to reduce or prevent a vertical transmission of the virus from a pregnant woman to a fetus or newborn and not how to treat the female specific manifestation of the disease. NIH Support For Research on Women's and Men's Health Issues Fiscal Years 1988, 1989, 1990, U.S. Department of Health and Human Services, Public Health Service, National Institute of Health, NIH Publication No. 92-3456 July 1991; CDC HIV/AIDS Prevention Fact Sheet, February 13, 1995. Women and Health Research, p. 66.

8. Through December 1994, the Centers for Disease Control and Prevention ("CDC") received reports of 58,428 cases of acquired immunodeficiency syndrome ("AIDS") among adult and adolescent (13 years and older) women in the United States. The population of women among cases in adults and adolescents has increased steadily, from 7 percent in 1985 to 18 percent in 1994. CDC HIV/AIDS Prevention Newsletter, Facts About Women and HIV/AIDS, February 13, 1995.

Health Service 73. If *Winters* is upheld, elimination of the doctrine of *contra proferentum* coupled with the lack of data pertaining to women's health issues will result in an increased denial of coverage for treatments for women. Women consumers challenging these decisions, even when based on ambiguous policy terms, will succeed in obtaining coverage only when plan administrators are found to have abused their discretion.

The neglect of women's health issues also increases the likelihood that insurance companies will exclude health care services for women based on a determination that a treatment is "not medically necessary." The *Winters* decision allows ERISA plan administrators to be, in effect, the sole arbiters of what is medically necessary. The current trend of insurance carriers towards discharging mothers and their babies within as little as eight hours after delivery illustrates risks involved when insurance companies and not doctors decide what is medically necessary. Despite the fact that there is little research to evaluate the health effects of early discharge policies, insurance companies have determined that longer stays are not medically necessary. Paula Braveman, *et al.*, Early Discharge of Newborns and Mothers: A Critical Review of the Literature, Pediatrics (forthcoming August, 1995 in the Periodical of Pediatrics). By reducing the length of hospital stays for mothers and babies, insurance companies have reduced the cost of care. Since maternity care is routinely covered in almost all insurance plans, the financial decision to reduce the length of stays under the ambiguous "not medically necessary" exclusions is having an enormous effect nationally on the health care that women and their newborn babies receive. The lack of data evaluating the impact of early discharge from the hospital will make such practices virtually impossible to challenge without the doctrine of *contra proferentem.*

Failure to apply the doctrine of *contra proferentem* to ERISA

plans is inherently discriminatory and seriously detrimental to the lives and health of women.

II.

IF THE NINTH CIRCUIT OPINION IS UPHELD, WOMEN WILL BE UNIQUELY DISADVANTAGED UNDER THE ARBITRARY AND CAPRICIOUS STANDARD.

The doctrine of *contra proferentum* is needed as a threshold presumption for the purposes of creating a more equitable balance of power between the insurer and the insured. Without the doctrine, ERISA plan administrators have virtually complete discretion under an arbitrary and capricious (*i.e.* abuse of discretion) standard of review. Women in particular are at greater risk than men for denials of medical benefits for insurance coverage, as a result of the paucity of medical knowledge of women's health issues for the reasons more fully set forth in Point I, *supra.* Plan administrators, even though charged with a fiduciary responsibility, are only found to have abused their discretion when they fail to meet the arbitrary and capricious standard of review mandated by *Firestone Tire & Rubber Co. v. Bruch,* 489 U.S. 101, 109 S. Ct. 948 (1989). As demonstrated below, bound only by the arbitrary and capricious standard of review, courts have been forced to uphold decisions made by plan administrators even when the decisions conflicted with leading medical evidence, were inconsistent with prior company decisions, or were made pursuant to vague and unclear contract provisions.

This arbitrary and capricious standard requires that the court give deference to the decision of the plan administrator provided that the decision was not made arbitrarily. *Id.* According to *Firestone*, when the administrator is also the insurer and operates

under a conflict of interest, a less deferential scope of review is afforded. *Id.* However, even when this less deferential standard of review is applied, plan administrators regularly deny coverage under ambiguous exclusionary provisions. As a result, there has been much litigation initiated by women regarding benefit denials and, in particular, the cases involve a medical procedure known as high dose chemotherapy with autologous bone marrow transplant ("HDC/ABMT") used to treat breast cancer. *See, White v. Caterpillar, Inc.*, 765 F. Supp. 1918 (W.D. Mo. 1991); *Adams v. Blue Cross/Blue Shield of Maryland*, 757 F. Supp. 661 (D.C. Md. 1991); *Bucci v. Blue Cross/Blue Shield of Connecticut, Inc.*, 764 F. Supp. 728 (D. Conn. 1991). In those circuits in which the doctrine of *contra proferentem* is not law, litigants have lost the benefit of a threshold analysis which favors the insured.

William P. Peters, M.D., Ph.D., M.B.A, the Director of the Duke University Bone Marrow Transplant Program, one of the premier institutions in the country, and Mark C. Rogers, M.D., M.B.A., examined the consistency of preauthorization decisions by insurance companies for 533 women with breast cancer requiring HDC/ABMT from 1989 through 1992 (the "Duke Study"). William P. Peters and Mark C. Rogers, Variation in Approval by Insurance Companies of Coverage for Autologous Bone Marrow Transplantation for Breast Cancer, 330 New Eng. J. Med. 473 (1994). Preauthorization of payment for the medical procedure is generally required by the hospital prior to admission. Of these patients, 23% received denials by the insurers utilizing exclusionary provisions contained in the health insurance contract excluding coverage for women enrolled in clinical research trials (*i.e.* "experimental and/or investigational" treatment). The Duke Study concluded that ". . . [w]ith many insurers the outcome of the predetermination process [for HDC/ABMT for breast cancer] varies from request to request [and] is particularly disconcerting." *Id.* The study also concluded that the predetermination process, as applied to these breast cancer survivors, was "arbitrary and capricious" and that the ". . . process of predetermination by insurers did not correlate with protocol-based

medical decisionmaking, and it was a barrier to obtaining treatment." *Id.* Inasmuch as many of these women were catastrophically ill with breast cancer and had to thus suffer additional anguish and despair in coping with denials of coverage for life saving medical treatment, the plan administrators' arbitrary denials render such conduct unconscionable and certainly in breach of the fiduciary responsibility mandated by ERISA.

In *Holder v. Prudential Insurance Company of America,* 951 F.2d 89 (5th Cir. 1992), plaintiff was the beneficiary of a Prudential health insurance policy by virtue of his employment. Plaintiff's wife, also a beneficiary under the policy, was first diagnosed with breast cancer in 1987. The tumor and surrounding tissue were surgically removed shortly thereafter. After receiving standard dosages of chemotherapy, Mrs. Holder's cancer reoccurred a few months after the surgery. Her doctors suggested that she undergo HDC/ABMT. The terms of the insurance policy provided that the plan administrator had discretion to construe and interpret the plan provisions. The insurer in *Holder* denied plaintiff coverage based on the "experimental" term in the exclusionary portion of the summary plan description. As has been generally acknowledged, benefits for medical coverage are deemed to be within the grant of coverage of a plan unless specifically excluded. Utilizing the applicable arbitrary and capricious standard of review, the court completely deferred to the decision of the administrator.

In *Holder* the insurer routinely paid for chemotherapy to treat breast cancer, and indeed had paid for previous chemotherapy for Mrs. Holder. The plan neither limited the amount of chemotherapy to which Mrs. Holder was entitled, nor specified the drugs approved for her use thus creating ambiguity. Despite this patent ambiguity, when coverage for HDC/ABMT was sought, the denial was upheld by the court. Had *contra proferentem* been utilized, the court's inquiry would have been focused on the reasonableness of the administrator's construction of the ambiguous policy terms. Absent the benefit of the doctrine, the abuse of discretion standard supported

the insurance company's position that its denial of coverage was justified.

Likewise, in *Thomas v. Gulf Health Plan, Inc.*, 688 F. Supp. 590 (S.D. Ala. 1988), plaintiff Janice Thomas was diagnosed with breast cancer, and she immediately underwent surgery. The cancer reoccurred and Mrs. Thomas' physician treated her further with eight cycles of various chemotherapy drugs. Once the cancer failed to respond to this regime, Mrs. Thomas' physician recommended that she receive HDC/ABMT. The defendant insurance company precertified the costs associated with the bone marrow harvesting and the three day hospital stay. Thus, part of the treatment was covered. The plan administrator, however, later denied the plaintiff's request for coverage, under an ambiguous exclusion which denied insurance coverage for "experimental" treatments. The court upheld the denial stating that the decision was ". . . rational and [made] in good faith". The court also stated that "[i]t is undisputed that, as it relates to the treatment of breast cancer, [HDC/ABMT] is experimental." The fact that the same insurance company, operating under the identical plan, had paid for this treatment in the past was given no importance. Inconsistency in applying the terms of an insurance plan is evidence of an ambiguous contract and yet the *Thomas* court deferred to the decision of the administrator in upholding the claims denial. Had *contra proferentem* been applied, the decision would have clearly favored Mrs. Thomas thereby protecting her from the contracts ambiguity. Again, the arbitrary and capricious standard was insufficient to protect the rights granted to Mrs. Thomas. *See also*, *Lowery v. Healthchicago Inc.*, 1994 U.S. Dist. Lexis 6380 (N.D. Ill. 1994) (where the court upheld the plan administrator's denial of plaintiff's request for coverage despite the insurer's failure to adequately review the request for coverage under its own internal guidelines).

In *Bechtold v. Physicians Health Plan of Northern Indiana, Inc.*, 19 F.3d 322 (7th Cir. 1994), an ambiguity in the policy was created by

cross-referencing another manual to define its terms without providing the beneficiary with a copy of that manual. The spirit of ERISA, mandating full disclosure of all insurance policy provisions, was ill served by this omission. The court held that ". . . the clear and unambiguous language of the policy dictates that the defendant . . . properly denied coverage for the HDC/ABMT treatment." *Id.* at 325. Certainly, since the summary plan description incorporated terms of another plan, which was not given to Mrs. Bechtold, the exclusion of HDC/ABMT as a treatment for breast cancer was anything but "clear". Mrs. Bechtold, a forty-two year old woman, whose cancer reoccurred after having a modified radical mastectomy, clearly needed to have the playing field leveled. The doctrine was needed to protect her from contract provisions which deliberately created an ambiguity. By supplying its insureds with only half of the contractual terms, the defendant maintained complete supremacy and gave itself authority to make post hoc coverage determinations by keeping insureds ignorant of the meaning of the policy terms.

Similarly, in *Johnson v. District 2 Marine Engrs. Ben. Assn.*, 857 F.2d 514 (9th Cir. 1988), the plan administrator denied plaintiff's request for a liver transplant, which was her only chance for survival. The contract was initially silent about coverage for transplants. Following the submission of Mrs. Johnson's request, the insurance company amended the policy to specifically exclude organ transplants. The court held that there was no arbitrary conduct since the administrator stated that it was never the Plan's intention to include the cost of transplants within the scope of coverage. The court further noted that the precarious state of the insurer's finances compelled the administrator to exclude transplants from coverage. It reasoned that given the financial status of the company, it could not possibly have intended to include the cost of transplants as a covered expense. Essentially, by reaching this conclusion, the court implied that the insured should be able to determine the intent of the plan's drafters, even where such intent was not stated in the terms of the plan. This case is illustrative of the dire need for a balancing of the

equities between the insurer and insured. The doctrine of *contra proferentem* would have protected Mrs. Johnson against this arbitrary denial. Because transplants were not specifically excluded from coverage, any ambiguity would have been construed against the insurer. By failing to apply this doctrine, the court essentially approved the practice of orally amending insurance contracts to exclude coverage for treatment after a request for a payment. This holding, as well as the aforementioned, violates the spirit of ERISA which was enacted to guarantee the benefits promised to employee beneficiaries and their families.

CONCLUSION

For the foregoing reasons, this Court should hold that the doctrine of *contra proferentem* applies to decisions made by ERISA plan administrators.

Respectfully submitted,

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